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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,163	12/21/2001	Audra L. Stinchcomb	ACP-0001	6957

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,163	STINCHCOMB, AUDRA L.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicant's election, filed 07/09/2003.

Under rule 1.126, claim 29 presented in the original claims has been renumbered as claim 28.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-11 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the subject matter of Groups I, II, III, and IV are sufficiently related that a thorough search for the subject matter of one would encompass a search for the subject matter of the others. This is not found persuasive. With regard to the process Groups I, III, and IV: the process of Group I is distinct from the process of Group III and Group IV because Group I requires a population of patients that have illness. There is no requirement like this in Group III or Group IV. Group III is prophylactic treatment. Group IV is an *in vitro* process that requires a skin sample, not a patient. Regarding the product of Group II is distinct from any of the processes of Groups I, III and IV, and the product can be used in a materially different process other than the processes of Groups I, III and IV. For example the product of Group II can be used to treat pain as disclosed by US 6,132,762 or it can be used for improving disturbed behavior and elevated mood in patients suffering from

dementia as disclosed by US 5,804,592.The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, but also it is extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicant presents four distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim.

Claims 1-11 are included in the prosecution.

Claim Objections

3. Claims 1, 7 and 11 are objected to because of the following informalities: the claims contain the referral chemical numbers of the compounds. Appropriate correction is required. The examiner suggests replacing the numbers by the chemical formulae of the claimed compounds.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Touitou et al.

Touitou et al. disclosed transdermal delivery of tetrahydrocannabinol, i.e. THC (title). THCs are used as anti-emetics that employed to overcome nausea and vomiting that results from the administration of cancer chemotherapeutics (introduction; page 14, left col., first full paragraph). THC included delta 8 derivative and is included in topical formulations (page 12, left col., second full paragraph).

The limitations of claims 1, 6, and 8 are met by the Touitou's reference.

6. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,328,992 ('992).

US '992 disclosed transdermal structure for delivering cannabis for the treatment of nausea and pain associated with cancer chemotherapy and wasting associated with

AIDS, that reads on claims 1 and 6 (abstract; col.1, lines 24-30). Cannabis means any one or more or mixture of compounds or chemical components including delta 8THC, delta 9 THC, cannabinol, cannabidiol, that reads on claims 1 and 7 (col.2, lines 47-53; col.7, lines 54-58). The transdermal structure comprises patches, bandages or covering, that reads on claims 8 and 9 (col.1, lines 58-60). The patch is occlusive and comprises backing layer; rate controlling membrane; reservoir positioned between the backing and the rate controlling membrane and comprises the active agent in a suitable carrier; and an adhesive means, that reads on claims 2, 3, and 5 (col.2, lines 6-10, 21-24; col.3, lines4-8, 25-28, 49-51, 64-67; col.4, lines 66-67; col.5, line 1). The suitable carrier includes gel, that reads on claim 4 (col.3, lines 37-45).

The limitations of claims 1-9 are met by the US '992 reference.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '992.

The teachings of US '992 are discussed under 102 rejection above. The reference, however, does not teach the particular combination of cannabis derivatives as recited in claim 11.

The art recognized the combination of cannabis derivatives in a transdermal device used to treat nausea and vomiting associated with cancer chemotherapy and wasting associated with AIDS, as disclosed by US '992. No criticality shown by the particular combination of cannabis derivatives as claimed in claim 11, absent evidence to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the transdermal device disclosed by US '992 and combine many derivatives of cannabis in the reservoir of the device as indicated by the patient's particular condition, motivated by the teaching of US '992 that the transdermal method of delivery of cannabis derivatives provides controlled release of these drugs, with reasonable expectation of having a transdermal device comprising combination of cannabis derivatives as claimed in claim 11 that provides effective relief of nausea and vomiting.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Touitou et al. or US 992 in view of PGPB 2003/0158191 ('191).

The teachings of each of Touitou's reference and US '992 are discussed under 102 rejection above.

The references do not teach the inclusion of opiate with the transdermal delivery of cannabis derivatives.

PGPB '191 teaches a combination of cannabis derivatives delivered transdermally with other active agents including morphine page 2, 0012; page 10, 0214;

page 14, 0356; page 15, 0359, 0362). The reference teaches that the combination therapy may allow for increased efficacy and potentially reduces side effects (page 16, 0370).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cannabis derivatives delivered transdermally as taught by any of Touitou or US '992 and add opiate in the transdermal system as taught by PGPB '191, motivated by the teaching of PGPB '191 that the combination therapy may allow for facilitating increased efficacy and potentially reduces side effects, with reasonable expectation of having a device that delivers cannabis derivatives and opiate with increased efficacy and reduced side effects.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou or US '992 in view of Pugh et al. reference.

The teachings of each of Touitou's reference and US '992 are discussed under 102 rejection above.

The references do not teach the inclusion of opiate with the transdermal delivery of cannabis derivatives.

Pugh teaches a combined administration of delta 9 THC and morphine results in a greater than additive effect (abstract).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide THC delivered transdermally as taught by any of Touitou or US '992 and add opiate in the transdermal system as taught by Pugh,

motivated by the teaching of Pugh that the combined administration of delta 9 THC and morphine results in a greater than additive effect, with reasonable expectation of having a transdermal device that delivers THC and opiate with increased efficacy.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali